DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-002

February 12, 2015

Fukuda Denshi USA, Inc.
Mr. Doug Blakely
Director-Regulatory Affairs
17725 NE 65th Street, Building C
Redmond, WA 98052

Re: K134046
Trade/Device Name: Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX

Dear Mr. Blakely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K134046**

Device Name: **Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor**

Indications For Use:

Use of the Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor is indicated in those situations where observation of one or more of the following parameters on an individual patient may be required. ECG (waveform, heart rate, ST-Level and ventricular arrhythmias), respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO_2), carboxyhemoglobin saturation (SpCO)*, methemoglobin saturation (SpMet)*, total hemoglobin concentration (SpHb)*, plethysmograph, temperature, invasive blood pressure (IBP), cardiac output, and carbon dioxide concentration (CO_2). *: DS-8100M only The target populations of the system are adult, pediatric and neonatal patients with the exception of the ST segment, arrhythmia analysis, and SpHb, for which the target populations are adult and pediatric excluding neonates. These observations can include an audible and visual alarm if any of these parameters exceed values that are established by the clinician. The observations may include the individual or comparative trending of one or more of these parameters over a period of up to 24 hours. The DS-8100N/8100M Patient Monitor is indicated in situations where an instantaneous display of waveform, numeric and trended values is desired. The DS-8100N/8100M Patient Monitor is also indicated where a hard copy record of the physiological parameters, the alarms conditions or the trended values may be required.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 870.92.

The assigned 510(k) number is: K134046.

Submitter: Fukuda Denshi USA, Inc.
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- Contact Person: Doug Blakely
  Director- Regulatory Affairs
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  17725 NE 65th Street, Building C
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- Date Prepared: December 17, 2013

Device Name:

- **Proprietary Name:** Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor
- **Common Name:** Patient Monitor
- **Product Code:** MHX – Monitor, physiological, patient(with arrhythmia detection or alarms)
- **Regulation Number:** 21 CFR Part 870.1025
- **Device Class:** II
- **Review Panel:** Cardiovascular

510(k) Summary
Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor

Legally Marketed Predicate Devices:

- Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor (Model: DS-7210/7210M), 510(k) # **K083697**

  In addition, function of the DS-8100N/8100M Patient Monitor utilizes technology incorporated into previously cleared devices and OEM manufactured module that have received separate clearance from the FDA as follows:

  The SpO_2 measurement module used in the DS-8100N system is the same as that used in the Covidien (Nellcor) model "OxiMax N-600x Pulse Oximeter" cleared under 510(k) # **K060576**.

  The SpO_2/ SpCO/ SpMet/ SpHb measurement used in the DS-8100M is the same as that used in the Masimo model "Masimo RADICAL 7 Pulse CO-Oximeter" cleared under 510(k) # **K110028**.

  The CO_2 measurement module used in the DS-8100N/8100M is the same as that used in the Oridion model "Capnostream20" cleared under 510(k) # **K094012**.

  The CO_2 measurement sensor connected to the DS-8100N/8100M is the same as the Respironics model "Capnostat 5 Mainstream CO_2 Sensor" cleared under 510(k) # **K042601**.

Description:

The Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor is meant to acquire and monitor physiological signals from patients. The system is design to be used in ICU, CCU, OR, ER, or Recovery areas of the hospital or clinic. Patient ages from neonates to adults can all be monitored. Waveforms, numeric and trend data from these patients are available to the clinician on the systems display or may be printed on the system's recorder.

The DS-8100N/8100M provides monitoring of ECG (Up to 7lead), heart rate, respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO_2), plethysmograph, and parameters in combination of invasive blood pressure (IBP) (max. 2ch.), temperature (max. 4ch.), and cardiac output (max. 1ch.) using the multiparameter connector. In addition, the DS-8100M provides monitoring of carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb). The DS-8100N for SpO_2 measurement utilizes a technology of an OxiMax N-600x Pulse Oximeter manufactured by Nellcor and previously cleared under 510(k) # **K060576**. The DS-8100M for SpO_2, SpCO, SpMet, and SpHb measurement

510(k) Summary
Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor

utilizes a technology of a Masimo RADICAL 7 Pulse CO-Oximeter manufactured by Masimo and previously cleared under 510(k) # **K110028**. All parameter connectors are on the front panel and are labeled on the left side of the main unit. By connecting the optional CO_2 Gas Unit (HCP-800/HCP-810) or Gas Unit I/F (HPD-800/HPD-810) to the AUX Connector on the rear side of the main unit, it provides monitoring of carbon dioxide concentration (CO_2) The CO_2 Gas Unit (HCP-800/HCP-810) that utilizes Oridion Medical 1987 Ltd. technology "Microstream®" and previously cleared under 510(k) #**K094012.** The Gas Unit I/F (HPD-800/HPD-810) allows to connect the Capnostat 5 Mainstream CO_2 Sensor, 510(k) #**K042601**, manufactured by Respironics Novametrix, LLC. to the main unit with serial communication protocol for CO_2 monitoring.

The DS-8100N/8100M is a self-contained monitor, which includes a 10.2 inch TFT color LCD display which can display up to 14 waveforms and up to 14 numeric displays. The user interfaces, the touch screen panel, is located on the front of the main unit. The transparent area covering the display has a variable number of keys that are activated by software and depend on the display/function that the user selects. And there are five (5) fixed keys (Alarm Silence, NIBP Start/Stop, Home, Menu, and Prev. Disp.) and Jog Dial on the right side of the front of the main unit. The infrared remote-control command is also available (optional). By attaching the optional Recorder Unit (HR-800) or Recorder/Expansion Port Unit (HR-811), a dot matrix thermal printer, on the bottom of rear of the main unit, it provides hard copy recordings of all monitored parameters and can print up to three (3) waveforms simultaneously. In addition, the Recorder/Expansion Port Unit (HR-811) contains the Analog Output Connector that outputs the ECG and BP waveforms, including the QRS SYNC output signal, VGA Output Connector, and Module-LAN Connector, which connects to other patient monitor. By attaching the Expansion Port Unit (CU-810) on the bottom of rear of the main unit, it provides the VGA Output Connector, and Module-LAN Connector, which connects to other patient monitor or connects to the laser printer as general LAN.

Additional standard features include DS-LAN connection, which is a proprietary network system based on an Ethernet LAN (#K**970585**), through a built in Ethernet LAN, and a wireless connection using the optional telemetry transmitting module (Model: HLX-801) and a wireless bidirectional communication using the optional Bidirectional Wireless Communication Module (Model: HTC-702) allow remote monitoring when combined with Fukuda Denshi Central Station Monitors. An option battery operation allows a patient to continue to be monitored during intra-hospital transport.

The DS-8100N/8100M is small and lightweight at 3.5 kg. The physical dimensions of the device are 300 mm (W) x 265 mm (H) x 75 mm (D).

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Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor

The option Recorder Unit (HR-810) weight is 0.7 kg. The physical dimensions of the device are 100 mm (W) x 110 mm (H) x 178 mm (D).
The option Recorder/Expansion Port Unit (HR-811) weight is 0.8kg. The physical dimensions of the device are 100 mm (W) x 110 mm (H) x 178 mm (D).
The option Expansion Port Unit (CU-810) weight is 0.45kg. The physical dimensions of the device are 50 mm (W) x 110 mm (H) x 178 mm (D).

The option Gas Unit I/F (HPD-800/HPD-810) weight is 0.3kg/0.18kg. The physical dimensions of the device are 36 mm (W) x 91 mm (H) x 87 mm (D).
The option CO2 Gas Unit (HCP-800/HCP-810) weight is 0.4kg/0.22kg. The physical dimensions of the device are 36 mm (W) x 91 mm (H) x 87 mm (D).

Statement of Intended Use:

The Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor provides a simple and reliable method to display and document the continuous hemodynamic, cardiovascular observations that are typically required of critically ill patients. The target populations of the system are adult, pediatric, and neonatal patients, who may be located in a hospitals ICU, CCU, OR, ER, recovery or other critical care area, with the exception of the ST segment, arrhythmia analysis, and SpHb, for which the target populations are adult and pediatric excluding neonates. The DS-8100N/8100M monitor can also be used to follow patients whose treatment requires close observation of specific physiological parameters. These patients may be in a clinic or other healthcare environment under the care of a physician.

The availabilities of DS-LAN connection, through a built in Ethernet LAN, and a wireless connection using the optional telemetry transmitting module (Model: HLX-801) and a wireless bidirectional communication using the optional Bidirectional Wireless Communication Module (Model: HTC-702) allow remote monitoring when combined with Fukuda Denshi Central Station Monitors.
An option battery operation allows a patient to continue to be monitored during intra-hospital transport.

Parameters such as ECG, heart rate, respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO_2), carboxyhemoglobin saturation (SpCO)*, methemoglobin saturation (SpMet)*, and total hemoglobin concentration (SpHb)*, plethysmograph, temperature, invasive blood pressure (IBP), cardiac output, and carbon dioxide concentration (CO_2) may be monitored individually or in any grouping required by the clinician. *: DS-8100M only

The Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor is not recommended for home use, when it has not been ordered by a physician.

510(k) Summary
Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor

Indications for Use:

Use of the Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor is indicated in those situations where observation of one or more of the following parameters on an individual patient may be required. ECG (waveform, heart rate, ST-Level and ventricular arrhythmias), respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO2), carboxyhemoglobin saturation (SpCO)*, methemoglobin saturation (SpMet)*, total hemoglobin concentration (SpHb)*, plethysmograph, temperature, invasive blood pressure (IBP), cardiac output, and carbon dioxide concentration (CO2). *: DS-8100M only The target populations of the system are adult, pediatric and neonatal patients with the exception of the ST segment, arrhythmia analysis, and SpHb, for which the target populations are adult and pediatric excluding neonates. These observations can include an audible and visual alarm if any of these parameters exceed values that are established by the clinician. The observations may include the individual or comparative trending of one or more of these parameters over a period of up to 24 hours. The DS-8100N/8100M Patient Monitor is indicated in situations where an instantaneous display of waveform, numeric and trended values is desired. The DS-8100N/8100M Patient Monitor is also indicated where a hard copy record of the physiological parameters, the alarms conditions or the trended values may be required.

Technological Characteristics:

The DS-8100N/8100M incorporates the identical technology as the predicate devices. The device provides a means with interfacing with a patient, collecting parameter specific physiological data and processing the data for alarm generation, display of numeric values and waveforms at bedside or at a central monitoring station.

The technology characteristics of the DS-8100N/8100M do not affect the safety or efficacy of the device. Any safety issues raised by a software control medical device are either the same issues already addressed by the predicate devices or are addressed the system hazard analysis, or in the system validation.

510(k) Summary
Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor

Testing:

The Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor has been subjected to extensive safety, environmental and performance testing. Final testing for the device included various performance test for the device designed to insure that all functional and performance specifications were met. Additionally the device was host tested at the previously noted OEM engineering test facility to insure that performance and functional specifications for their supplied module were met.

The DS-8100N/8100M has also been tested to assure compliance to the requirement of various published standards including the following:

General safety standards

- UL60601-1: 2006
- IEC 60601-1-1: 2000
- IEC 62304: 2006
- IEC 62366: 2007
- IEC 60601-1-8: 2006
- ISO 14971: 2007

EMC standards

- IEC 60601-1-2 Ed.3.0: 2007

Individual standards

- ANSI/AAMI EC13: 2002/(R)2007
- ANSI/AAMI EC53: 1995/(R)2008
- ANSI/AAMI EC57: 1998/(R)2008
- ANSI/AAMI SP10: 2002/(R)2008/A1: 2003/(R)2008/A2: 2006/(R)2008
- IEC 60601-2-27: 2005
- IEC 60601-2-30: 1999
- IEC 60601-2-34: 2000
- IEC 60601-2-49: 2001
- EN 12470-4: 2000/A1: 2009EN 980: 2008
- ISO 21647: 2004, including Cor 1: 2005
- ISO 9919: 2005

510(k) Summary
Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor

Conclusion:

In conclusion, drawing from laboratory testing, validation, and risk analysis, the Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor demonstrates that this device is as safe and effective and performs as well as the legally marketed predicate devices, the Fukuda Denshi DS-7000 Series Patient Monitor (Model: DS-7210/7210M) 510(k) # **K083697**, the Nellcor model "OxiMax N-600x Pulse Oximeter" 510(k) # **K060576** (SpO_2 portion), the Masimo model "RADICAL 7 Pulse CO-Oximeter" 510(k) # **K110028** (SpO_2/ SpCO/ SpMet/ SpHb portion), the Oridion Medical 1987 Ltd. model "Capnostream20" 510(k) # **K094012** (CO_2 portion), and the Respironics model "Capnostat 5 Mainstream CO_2 Sensor"510(k) # **K042601** (CO_2 portion).